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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/813,661	03/30/2004	John McMichael	13024/38628A	5210

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EXAMINER

HENLEY III, RAYMOND J

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 06/10/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/813,661	MCMICHAEL, JOHN	
	Examiner	Art Unit	
	Raymond J. Henley III	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>12/30/04 + 3/30/04</u> | 6) <input type="checkbox"/> Other: ____ |

CLAIMS 1-20 ARE PRESENTED FOR EXAMINATION

Applicant's Preliminary Amendment filed March 30, 2004 and Information Disclosure Statements filed March 30, 2004 and December 30, 2004 have been received and entered into the application. Accordingly, the specification at page 1 has been amended. Also, as reflected by the attached, completed copies of forms PTO/SB/08A and PTO/SB/08B, the Examiner has considered the cited references.

Claim Rejection - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 15-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lernmark et al. (U.S. Patent No. 6,025,176, cited by Applicant).

Lernmark et al. teach GAD antibody compositions which may comprise buffers, such as "Tris, phosphate, carbonate, etc., stabilizers, biocides, inert proteins, e.g., serum albumin, or the like" (col. 10, lines 38-47). It is also taught that "the excipient may be present in [sic] from about 1 to 99% of the total composition" (col. 10, lines 49-50) and that "[w]here an antibody capable of binding to the islet GAD autoantibody or the recombinant or synthetic GAD is employed in an assay, this will typically be present in a separate vial" (col. 10, lines 51-54). Because the antibodies of Lernmark et al. are taught to be useful for "diagnostic or therapeutic uses", such is believed to be indicative of a pharmaceutical utility, i.e., the statement of intended

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use in present claim 15 of "A pharmaceutical composition" is not seen to impart any physical or otherwise material feature to the claimed composition that is not in the composition of the reference.

The difference between the above and the claimed subject matter lies in that Lernmark et al. fail to teach the specifically claimed antibody amounts (present claims 15-18) and the specific types of GAD antibodies (present claims 19-20).

However, the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains because as noted above, it is taught that the compositions may comprise from 1 to 99% of excipient, which indicates that the antibody may be present at a concentration of 1%. The specific amount present would be variable and depend on the total size of the composition and it is not seen that the presently claimed concentrations would not be concentrations present in compositions that are taught by the reference. Also, the reference teaches GAD antibodies in general and thus would have encompassed the specific GAD antibodies claimed.

Double Patenting

Statutory

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The

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filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 1-20 are rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-20 of prior U.S. Patent No. 6,713,058 (McMichael, cited by the Examiner). This is a statutory double patenting rejection because the same invention is present in the currently pending claims and those the '058 patent.

Obviousness-type

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

I Claims 1-20 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-16 of U.S. Patent No. 6,436,401 (McMichael, cited by the Examiner). Although the conflicting claims are not identical, they are not patentably distinct from each other for the following reasons.

Present claims 1-14 are directed to alleviating symptoms of neuropathic conditions, such as would occur in a diabetic patient (see present claim 2, line 3). Such is believed to substantially overlap with patented claims 1-12 because such claims are directed to alleviating

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symptoms of diabetes in general (i.e., patented claim 1) and thus would have included the specific neuropathic symptoms of diabetes as is present claims.

Respecting present claims 15-20, the present preamble recited in claim 15, i.e., “for administration to a subject for alleviating symptoms of neuropathic conditions”, does not impart any physical or otherwise material feature to the presently claimed composition that is not present in the patented composition (i.e., patented claims 13-16). Also, patented claim 13 recites “anti-GAD antibodies” broadly and thus would have encompassed the specific anti-GAD antibodies of present claims 19-20. Finally, while patented claims 1 and 13 recite “less than 1.0 mg of anti-insulin antibodies” and none of the present claims require such an antibody, the present claims are not patentably distinct because (a) the term “comprising” is set forth in the present claims and thus opens the claims for inclusion of other components and (b) in the patented claim “less than 1.0 mg of anti-insulin antibodies” can reasonably interpreted as being an amount of 0 mg.

II Claims 1-20 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8, 24-26 and 33 of U.S. Patent No. 6,294,171 (McMichael, cited by Applicant). Although the conflicting claims are not identical, they are not patentably distinct from each other because as shown by patented claim 24, the objective of patented claim 1 of “treating the symptoms of a disease state associated with the presence of a toxin or infectious agent” would encompass an objective of treating the symptoms of diabetes. Also, because in both the patented claims and the present claims, anti-glutamic acid decarboxylase (anti-GAD) antibodies are administered for the purpose of treating the symptoms of diabetes, (patented claim 24 and present claim 1), the objective of treating the specific

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symptom of present claim 2, i.e., diabetic neuropathy, would be encompassed in the broad claims of the patent, i.e., claims 1 and 24.

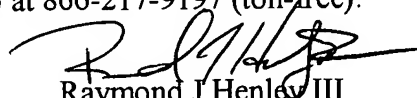
The patented claims are silent with respect to the specific anti-GAD antibodies of present claims 13, 14, 19 and 20. However, the patented claims recite "anti-glutamic acid decarboxylase" in general and is believed to have thus encompassed the species of the present claims. Also, while patented claim 33 does not recite the specific antibody amounts of present claims 17 and 18, it does recite "less than 0.1 mg" and thus would have included the specific amounts presently claimed.

Accordingly, for the above reasons, the claims are deemed properly rejected and none are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Raymond J. Henley III whose telephone number is 571-272-0575. The examiner can normally be reached on M-F, 8:30 am to 4:00 pm Eastern Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Raymond J Henley III
Primary Examiner
Art Unit 1614

June 7, 2005


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